PREPROPOSAL STATEMENT OF INQUIRY

CR-101 (June 2004)
(Implements RCW 34.05.310)
Do **NOT** use for expedited rule making

Agency: Department of Health

Subject of possible rule making: Chapter 246-102 WAC - Cancer Registry

Statutes authorizing the agency to adopt rules on this subject: RCW 70.54.230, 70.54.240, 70.54.250, 70.54.260, 70.54.270.

Reasons why rules on this subject may be needed and what they might accomplish: The Cancer Registries Amendment Act in 42 USC 280(e) requires that states receiving federal funds establish regulations to meet reporting requirements. The department must update the current rules in order to stay in compliance with the current federal regulations and standards and to maintain funding. The purpose of the rulemaking is to update, clarify and describe activities and responsibilities of the state cancer registry and reporting responsibilities for health care professionals and reporting entities.

Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies:
The Centers for Disease Control and Prevention National Program of Cancer Registries (NPCR) via: Public Law 102-515 and Public Law 107-260. NPCR issues program standards that state registries are expected to comply with.

Process for developing new rule (check all that apply):

- ☐ Negotiated rule making
- ☐ Pilot rule making
- ☐ Agency study
- ☒ Other (describe) Collaborative

How interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication:
(List names, addresses, telephone, fax numbers, and e-mail of persons to contact; describe meetings, other exchanges of information, etc.)

Interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication by providing comments via the DOH website or by contacting:

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DATE 07/22/09

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Chapter 246-102 WAC
Cancer registry

Last Update: 2/7/01

WAC Sections

246-102-001 Purpose.
246-102-010 Definitions.
246-102-020 Who must report.
246-102-030 Cancer case identification.
246-102-040 Data collection requirements.
246-102-050 Form, frequency, and format for reporting.
246-102-060 Data quality assurance.
246-102-070 Access and release of information.

246-102-001
Purpose.

The purpose of cancer case reporting is to monitor the incidence of cancer in the state. Information collected through the cancer registry system is used by medical, research and public health professionals to understand, control and reduce occurrences of cancer in residents of Washington. This chapter establishes the criteria and procedures for identifying and reporting cancer cases and defines the standards for access and release of cancer information.

[Statutory Authority: RCW 70.54.270, 43.20.050, 43.70.130. 01-04-086, § 246-102-001, filed 2/7/01, effective 3/10/01.]

246-102-010
Definitions.

For the purposes of RCW 70.54.230, 70.54.240, 70.54.250, 70.54.260, 70.54.270, and this chapter, the following words and phrases shall have the following meaning unless the context clearly indicates otherwise:

(1) "Cancer case" means:

(a) Any malignant neoplasm with the exception of basal and squamous cell carcinoma of the skin;

(b) All brain tumors;

(c) Basal and squamous cell carcinoma of the external genital organ sites (vulva, labia, clitoris, prepuce, penis, scrotum);

(d) Cancer in situ, except carcinoma in situ of the uterine cervix; or

(e) Other diagnoses necessary to meet the reporting requirements of the Center for Disease Control's National Program of Cancer Registries, the National Cancer Institute's Surveillance Epidemiology and End Results Program, the Commission on Cancer, and the North American Association of Central Cancer Registries (a copy is available for review at the department).

(2) "Cancer diagnosis or treatment facilities" means hospitals, surgical centers, outpatient radiation therapy centers, doctors' offices, independent clinical laboratories and any other facilities where cancer cases are diagnosed or treated.

(3) "Confidential information" means any information which could lead to the identification of cancer patients, cancer diagnosis or treatment facilities, independent clinical laboratories, or attending health care providers.

(4) "Contractors" means agencies designated by contract with the department of health to perform activities related to identification, collection, and processing of cancer data.

(5) "Department" means the Washington state department of health.

(6) "Designees" means hospital-based cancer registries and other persons or entities designated by the department to perform data collection activities.

(7) "Hospital-based cancer registry" means a cancer registry which is maintained by a hospital or other health care facility.

(8) "In situ" means tumors described as "in situ" by the pathologist reading the diagnostic report(s).

(9) "Institutional review board" means any board, committee, or other group formally designated by an institution, or authorized under federal or state law, to review, approve the initiation of, or conduct periodic review of research programs to assure the protection of the rights and welfare of human research subjects as defined in RCW 70.02.010.

(10) "Patient" means a case, suspected case or contact.

(11) "Principal health care provider" means the attending health care provider recognized as primarily responsible for diagnosis and treatment of a patient, or in the absence of such, the health care provider initiating diagnostic testing or treatment for the patient.

(12) "Reportable cancer case" means any cancer case diagnosed in a Washington state resident after the effective date of these rules.

(13) "Resident" means an individual residing in Washington state at the time of cancer diagnosis.

(14) "Stage of disease" means a cancer classification system encompassing attributes of a tumor as determined and described by:

(a) *Summary Staging Guide, Surveillance Epidemiology and End Results (SEER), Program, April 1977*; except when superseded by more up-to-date measures (a copy is available for review at the department); and

(b) *Manual for Staging of Cancer, 5th Edition, American Joint Committee on Cancer, (AJCC), 1998*, except when superseded by more up-to-date measures (a copy is available for review at the department).

(15) "State cancer registry" means the statewide cancer data base maintained by the department of health.

(16) "State cancer registry contract" means the legal agreement by which contractors are authorized to obtain information on reportable cancer cases. It also means the document specifying the contractors' obligations to the state cancer registry with respect to how and when information is collected, processed, and provided and how quality assurance standards are met.

[Statutory Authority: RCW 70.54.270, 43.20.050, 43.70.130. 01-04-086, § 246-102-010, filed 2/7/01, effective 3/10/01.]

246-102-020
Who must report.

By statute (RCW 70.54.240), the responsibility for identifying and reporting cases of cancer rests with health care facilities, independent clinical laboratories, and other principal health care providers. The department may, at its discretion, delegate some or all of these responsibilities to contractors or other designees. A list of the contractors and designees responsible for identifying and reporting cases of cancer diagnosed at specific sites in Washington is available for review at the department.

[Statutory Authority: RCW 70.54.270, 43.20.050, 43.70.130. 01-04-086, § 246-102-020, filed 2/7/01, effective 3/10/01.]

246-102-030
Cancer case identification.

(1) Contractors or designees shall identify reportable cancer cases diagnosed and treated at cancer diagnosis and treatment facilities.

(2) Cancer diagnosis or treatment facilities shall:

(a) Organize case finding documents by procedure or service date to permit identification of cancer cases; and

(b) Submit or make available, case finding documents including the following if maintained:

(i) Disease and operation indices for cancer cases;

(ii) Pathology and cytology reports;

(iii) New patient radiation logs;

(iv) New patient chemotherapy logs; and

(v) Other alternative case finding documents that are necessary to identify or verify reportable cancer cases;

(c) Cancer diagnosis or treatment facilities shall submit case finding documents by paper form, computer disk, or electronic file or make batched hard copy documents available for on-site review, within forty-five days of the date of service.

(3) On request, principal health care providers shall identify to contractors, designees, or the department reportable cancer cases diagnosed at facilities other than hospitals, surgical centers, and outpatient radiation therapy centers (as specified under WAC 246-102-030 and 246-102-040) unless the patient was hospitalized for additional cancer diagnosis or treatment services within one month of diagnosis.

[Statutory Authority: RCW 70.54.270, 43.20.050, 43.70.130. 01-04-086, § 246-102-030, filed 2/7/01, effective 3/10/01.]

246-102-040
Data collection requirements.

(1) Contractors or designees shall complete cancer abstracts for patients identified through cancer diagnosis and treatment facilities.

(2) Cancer diagnosis or treatment facilities shall provide contractors or their designees with access to pathology and cytology reports and all medical records pertaining to identified cancer cases.

(3) On request by the contractor, designee or the department, principal health care providers or their staff shall be responsible for completing cancer abstracts for patients diagnosed at facilities other than hospitals, surgical centers, and outpatient radiation therapy centers, unless the patient was hospitalized for additional cancer diagnosis or treatment services within one month of diagnosis.

(4) The following information items shall be included in cancer abstracts, providing the information is available from the patient's medical records:

(a) Patient information:

(i) Name;

(ii) Address at time of diagnosis;

(iii) Sex;

(iv) Race;

(v) Hispanic origin;

(vi) Birthdate;

(vii) Age at time of diagnosis;

(viii) Social Security number;

(ix) State or country of birth;

(x) Usual occupation;

(b) Diagnostic information:

(i) Date first seen for this cancer;

(ii) Primary site or sites;

(iii) Histologic type or types, behavior and grade;

(iv) Date of each diagnosis;

(v) Method or methods of diagnostic confirmation;

(vi) Stage of disease at diagnosis using:

(A) Summary stage; and

(B) AJCC system if maintained by the cancer diagnostic or treatment facility;

(vii) Sequence;

(viii) Laterality;

(c) First course of treatment information:

(i) Date of initial treatment;

(ii) All treatment modalities given as part of first course of therapy;

(d) Other information:

(i) Name and address of cancer diagnosis or treatment facility providing information;

(ii) Medical record number;

(iii) Name and address of principal health care provider; and

(iv) Other items necessary to meet the reporting requirements of the Center for Disease Control's National Program of Cancer Registries, the National Cancer Institute's Surveillance Epidemiology and End Results Program, the Commission on Cancer, and the North American Association of Central Cancer Registries (a copy is available at the department).

(5) The department may require submission of additional information from contractors or designees as needed to assess data reliability and validity.

(6) Contractors shall prepare detailed data collection protocols for inclusion in the state cancer registry contract.

[Statutory Authority: RCW 70.54.270, 43.20.050, 43.70.130. 01-04-086, § 246-102-040, filed 2/7/01, effective 3/10/01.]

246-102-050
Form, frequency, and format for reporting.

(1) Contractors or designees shall:

(a) Prepare electronic data files containing information from cancer abstracts in a format specified by the department; and

(b) Provide electronic files to the state cancer registry at intervals specified by written agreement with the department.

(2) On request by the contractor, designee or the department, principal health care providers shall complete and submit cancer abstracts to contractors, designees, or the department under WAC 246-102-020 and 246-102-030 within sixty days following a patient's cancer diagnosis date if the patient was not hospitalized for a cancer-related diagnosis or treatment within one month of diagnosis.

[Statutory Authority: RCW 70.54.270, 43.20.050, 43.70.130. 01-04-086, § 246-102-050, filed 2/7/01, effective 3/10/01.]

246-102-060
Data quality assurance.

(1) Contractors or designees shall:

(a) Assess the completeness and accuracy of case identification and data collection through computerized edit programs and on-site audits, or make available information and documentation for this purpose; and

(b) Maintain a system for retrieval of completed cancer abstracts for a period up to ten years.

(2) Cancer diagnosis or treatment facilities shall:

(a) Make available to the contractor, designee or the department, all case finding source documents and medical records for data quality assurance activities.

(b) Maintain a system for retrieval of case finding source documents and medical records for a period up to ten years.

(3) The department may require contractors or designees to make available all findings from data quality assurance activities for review and verification.

[Statutory Authority: RCW 70.54.270, 43.20.050, 43.70.130. 01-04-086, § 246-102-060, filed 2/7/01, effective 3/10/01.]

246-102-070
Access and release of information.

(1) Cancer registry information shall be used only for statistical, scientific, medical research and public health purposes. Contractors and designees must comply with chapter 70.02 RCW regarding the disclosure of patient health care information.

(2) The department may release confidential registry information for research purposes after the research project has

been reviewed and approved by an institutional review board and a confidentiality agreement is negotiated (a copy of the institutional review board procedures and application are available from the department).

(3) The department may release confidential registry information for projects to assess threats to public health or improve public health practice after the project has been reviewed and approved by the department and a data-sharing agreement is negotiated (a copy of the procedures for data-sharing agreements is available from the department).

(4) Cancer diagnosis or treatment facilities may require contractors or designees to sign an agreement of confidentiality regarding access and release of cancer data and prepare, administer, and maintain confidentiality oaths as needed.

(5) Cancer diagnosis or treatment facilities shall adhere to recommendations in RCW 70.54.260 regarding content of confidentiality agreement if confidentiality agreements are used.

(6) Cancer diagnosis and treatment centers shall make available to cancer patients printed information which describes the purpose of the state cancer registry, the statutory requirements which apply to health care facilities, independent clinical laboratories, and other principal health care providers to identify and report cases of cancer to the state cancer registry, and to protect the confidential information that is reported, the public health and research uses of information in the state cancer registry, the circumstances under which cancer registry information is disclosed for these purposes and the relevant RCW and WAC pertaining to the state cancer registry.

[Statutory Authority: RCW 70.54.270, 43.20.050, 43.70.130. 01-04-086, § 246-102-070, filed 2/7/01, effective 3/10/01.]

NATIONAL PROGRAM OF CANCER REGISTRIES
PROGRAM STANDARDS

Purpose: The purpose of these standards are to:

- Guide priorities and activities of funded programs over the next five years
- Provide objective measures of program progress
- Improve program processes that ultimately affect outcomes

The following are the National Program of Cancer Registries (NPCR) Program Standards as currently defined for the purposes of the Program Announcement. These standards are based on authority provided the CDC-NPCR under the Public Health Service Act and its subsequent amendments, and apply to all reportable cancers as defined in the Act and amendments. The NPCR Program Standards may change during the project period of the cooperative agreement.

All funded programs must meet the following standards for:

- Legislative authority.
- Administration.
- Electronic data exchange.
- Data content and format.
- Completeness/ timeliness/quality.
- Quality assurance.
- Data use and data monitoring.

I. Legislative Authority

a. The state/territory has a law authorizing a population-based central cancer registry.

b. The state/territory has legislation or regulations in support of the Public Law authorizing the National Program of Cancer Registries (NPCR).

II. Administration:

a. The central cancer registry maintains an operational manual that describes registry operations, policies and procedures. At a minimum the manual contains the following:

1. Reporting laws/regulations.
2. List of reportable diagnoses.
3. List of required data items.
4. Procedures for monitoring timeliness of reporting.
5. Procedures for receipt of data.

6. Procedures for database management including a description of the Registry Operating System (software).
7. Procedures for data processing operations.
8. Procedures for conducting death certificate clearance.
9. Procedures for implementing and maintaining the quality assurance/control program.
    a. Procedures for conducting follow-back to reporting facilities on quality issues. These procedures include rules for identifying when action or further investigation is needed.
    b. Procedures for conducting record consolidation.
    c. Procedures for maintaining detailed documentation of all quality assurance operations.
10. Procedures for conducting data exchange including a list of case-sharing agreements.
11. Procedures insuring confidentiality and data security.
12. Procedures for data release including access to and disclosure of information.
13. Procedures for maintaining and updating the operational manual.

b. The central cancer registry has management reports that monitor the registry operations and database.

III. Electronic Data Exchange

a. The central cancer registry uses and requires a standardized, NPCR-recommended data exchange record layout for the electronic exchange of cancer data. NPCR-recommended data exchange layouts include:
    1. For abstract reports: The NAACCR record layout version specified *in Standards for Cancer Registries Volume II: Data Standards and Data Dictionary.*
    2. For pathology reports: *NAACCR Standards for Cancer Registries Volume V: Pathology Laboratory Electronic Reporting.*

b. At a minimum, 95% of reports from hospitals are submitted to the central cancer registry in an electronic format (where the medical records are owned by the hospital).

c. At a minimum, 85% of reports from non-hospital reporting sources are submitted to the central cancer registry in an electronic format. (e.g. radiation therapy centers, ambulatory surgery centers, and in-state and out-of-state pathology laboratories where medical records are owned by the reporting source.)

d. At a minimum, 75% of reports from physician offices, identified as required to submit cancer cases to the central cancer registry, do so in an electronic format (where the medical records are owned by the physician). This includes responses from physicians to central cancer registry inquiries

e. The central cancer registry primarily uses a secure Internet-based, FTP, or encrypted email mechanism to receive data from all reporting sources.

IV. Data Content and Format

a. For all NPCR required reportable cases, the central cancer registry collects or derives all required data items using standard codes as prescribed by NPCR. (see III. a)

b. The central cancer registry uses a standardized, NPCR-recommended data exchange format to transmit data to other central cancer registries and NPCR. (see III. a.)

V. Data Completeness/Timeliness/Quality

a. Within 24 months of the close of the diagnosis year, at least 75% of physicians, surgeons, and all other health care practitioners diagnosing or providing treatment for cancer patients submit all reportable cases to the central cancer registry, except for cases directly referred to or previously admitted to a hospital or other facility providing screening, diagnostic or therapeutic services to patients in that State and reported by those facilities (based on PL 102-515).

b. Within 12 months of the close of the diagnosis year, the central cancer registry data meet the NPCR standards for the following two data quality criteria:
   1. Data are 90% complete based on observed-to-expected cases
   2. 97% pass an NPCR-prescribed set of standard edits.

c. Within 24 months of the close of the diagnosis year, the central cancer registry data meet the NPCR standards for the following five data quality criteria:
   1. Data are 95% complete based on observed-to-expected cases
   2. There are 3% or fewer death-certificate-only cases
   3. There is a 1 per 1,000 or fewer unresolved duplicate rate
   4. The percent missing for critical data elements are:
      (a) 2% or fewer age
      (b) 2% or fewer sex
      (c) 3% or fewer race
      (d) 2% or fewer county
   5. 99% pass an NPCR-prescribed set of standard edits.

d. Within 12 months of the close of the diagnosis year, the central cancer registry exchanges data with other central cancer registries where a data-exchange agreement is in place.
   1. Regardless of residency, the central cancer registry collects data on all patients diagnosed and/or receiving first course of treatment in the registry's state/territory.
   2. The recommended frequency for data exchange is, at a minimum, two times a year.
   3. Exchanged data must meet the following minimum criteria:
      a. Exchange agreements are in place with all bordering central cancer registries.
      b. Exchanged data include a dataset that consists of NPCR core data items.
      c. 99% of data pass an NPCR-prescribed set of standard edits..
      d. The dataset is transmitted via secure encrypted Internet-based system.
      e. A standardized, NPCR-recommended data exchange format is used to transmit data. (see III. a.)

VI. Data Quality Assurance

a. The central cancer registry has an overall program of quality assurance that is defined in the registry operations policy and procedure manual. The quality assurance program consists of, but is not limited to:
   1. A designated certified tumor registrar (CTR) is responsible for the quality assurance program.
   2. Qualified, experienced CTR(s) conduct quality assurance activities.
   3. At least once every 5 years, case-finding and/or re-abstracting audits from a sampling of source documents are conducted at each hospital-based reporting facility.
   4. Data consolidation procedures are performed according to an accepted protocol.
   5. Procedures are performed for follow-back to reporting facilities on quality issues.

b. The central cancer registry has a designated education/training coordinator who is a CTR to provide training to the central cancer registry staff and reporting sources to assure high quality data.

VII. Data Use

a. Within 12 months of the end of the diagnosis year with data that are 90% complete, the central cancer registry produces preliminary pre-calculated data in tables in an electronic data file or report of incidence rates, counts, or proportions for the diagnosis year for Surveillance Epidemiology and End Results (SEER) site groups.

b. Within 24 months of the end of the diagnosis year with data that are 95% complete, the central cancer registry produces pre-calculated data in tables in an electronic data file or report. The report includes, at a minimum, age-adjusted incidence rates and age-adjusted mortality rates for the diagnosis year by sex for SEER site groups, and, where applicable, by sex, race, and ethnicity.

c. The central cancer registry, state health department, or its designee uses registry data for planning and evaluation of cancer control objectives in at least three of the following ways annually:
   1. Comprehensive cancer control.
   2. Detailed incidence/mortality estimates.
   3. Linkage with a statewide cancer screening program to improve follow-up of screened patients.
   4. Health event investigation(s).
   5. Needs assessment/program planning.
   6. Program evaluation.
   7. Epidemiologic studies.

VIII. Data Submission

The central cancer registry annually submits a data file to the NPCR-Cancer Surveillance System (CSS) that meets the reporting requirements outlined in the NPCR-CSS Submission Specifications document and meets criteria for publication in *United States Cancer Statistics*

IX. Collaborative Relationships

a. The central cancer registry actively collaborates in the state's comprehensive cancer control planning efforts.

b. The central cancer registry establishes a working relationship with all components of the cancer prevention and control program to ensure the use of registry data to assess and implement cancer control activities.

c. The central cancer registry establishes and regularly convenes an advisory committee to assist in building consensus, cooperation, and planning for the registry. Representation should include key organizations and individuals both within (such as representatives from all cancer prevention and control components) and outside the program (such as hospital cancer registrars, the American Cancer Society, clinical-laboratory personnel, pathologists, and clinicians).